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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : DiStefano *et al.*  
Serial No. : 10/656,530  
Filed : September 5, 2003  
Title : REGULATION OF THE GROWTH HORMONE/IGF-1 AXIS

Art Unit : 1645  
Examiner : Unknown

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

The Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request. A copy of a communication from a foreign patent office in a counterpart application is also enclosed.

This statement is being filed before the receipt of a first Office Action on the merits.

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Applicant : DiStefano *et al.*  
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Page : 2 of 2

Attorney's Docket No.: 13407-020001

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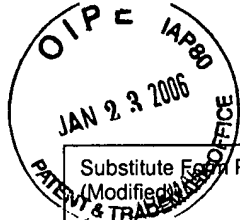
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 13407-020001	Application No. 10/656,530
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))		Applicant <b>DiStefano et al.</b>	
		Filing Date <b>September 5, 2003</b>	Group Art Unit <b>1645</b>

### U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	4,224,199	09/23/1980	Meyers et al.			
	AB	5,770,687	06/23/1998	Hornik et al.			
	AC	5,811,392	09/22/1998	Gilon et al.			
	AD	5,929,040	07/27/1999	Werther et al.			
	AE	5,942,489	08/24/1999	Schally et al.			
	AF	5,962,409	10/05/1999	Deghenghi			
	AG	5,981,533	11/09/1999	Traxler et al.			
	AH	6,057,422	05/02/2000	Schally et al.			
	AI	6,180,636	01/30/2001	Traxler et al.			
	AJ	6,242,199	06/05/2001	Pai et al.			
	AK	6,251,865	06/26/2001	Clark et al.			
	AL	6,284,741	09/04/2001	Werther et al.			
	AM	6,337,338	01/08/2002	Kozlowski et al.			
	AN	6,395,733	05/28/2002	Lee et al.			
	AO	20030087806	05/08/2003	Danko et al.			
	AP	6,573,293	06/03/2003	Tang et al.			
	AQ	20050201938	09/15/2005	Bryant et al.			

### Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AR	WO 02/072780	09/19/2002	WIPO				
	AS	WO 02/102804	12/27/2002	WIPO				
	AT	WO 02/102805	12/27/2002	WIPO				
	AU	WO 03/000688	01/03/2003	WIPO				
	AV	EP 1 284 144	02/19/2003	Europe				
	AW	WO 03/018021	03/06/2003	WIPO				

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AX	WO 03/018022	03/06/2003	WIPO				

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AY	Baldelli et al., "Growth hormone secretagogues as diagnostic tools in disease states," <i>Endocrine</i> , 14(1):95-9, February 2001.
	AZ	Bartke et al., "Extending the lifespan of long-lived mice," <i>Nature</i> 414(6862):412, November 22, 2001.
	AAA	Bartke and Clancy, "Dietary restriction and life-span," <i>Science</i> 296:2141-42, June 21, 2002.
	ABB	Bartke et al. "Genes that prolong life: relationships of growth hormone and growth to aging and life span," <i>J. Gerontol. Biol. Sci.</i> 56(8):B340-9, August 2001.
	ACC	Blum et al. "Substrate competitive inhibitors of IGF-1 receptor kinase," <i>Biochemistry</i> 39(51):15705-12, December 26, 2000.
	ADD	Carter et al., "A critical analysis of the role of growth hormone and IGF-1 in aging and lifespan," <i>TRENDS in Genetics</i> , 18(6):295-301, June 2002.
	AEE	Culler et al. "Somatostatin receptor subtypes: targeting functional and therapeutic specificity," <i>Ann. Endocrinol. (Paris)</i> 63(2 Pt 3):2S5-12, April 2002.
	AFF	Deghengi et al., "Somatostatin octapeptides (lanreotide, octreotide, vapreotide, and their analogs) share the growth hormone-releasing peptide receptor in the human pituitary gland," <i>Endocrine</i> , 14(1):29-33, February 2001.
	AGG	DiMartino et al. "The Hox cofactor and proto-oncogene Pbx1 is required for maintenance of definitive hematopoiesis in the fetal liver," <i>Blood</i> 98(3):618-626, August 1, 2001.
	AHH	Flurkey et al., "Lifespan extension and delayed immune and collagen aging in mutant mice with defects in growth hormone production," <i>Proc. Natl. Acad. Sci. U S A.</i> 98(12):6736-41, June 5, 2001.
	AII	Garcia de la Torre et al., "Antiangiogenic effects of somatostatin analogues," <i>Clin. Endocrinol.</i> 57:425-441, 2002.
	AJJ	Garcia et al., "PI3K is involved in the IGF-I inhibition of TSH-induced sodium/iodide symporter gene expression," <i>Mol. Endocrinol.</i> 16(2):342-52, February 2002.
	AKK	Ghigo et al., "Hypothalamic growth hormone-insulin-like growth factor-I axis across the human life span," <i>J. Pediatr. Endocrinol. Metab.</i> 13 Suppl 6:1493-502, 2000.
	ALL	Hailey et al., "Neutralizing anti-insulin-like growth factor receptor 1 antibodies inhibit receptor function and induce receptor degradation in tumor cells," <i>Mol. Cancer Ther.</i> 1(14):1349-53, December 2002.
	AMM	Hintz et al. "Prediabetic insulin resistance is not permissive to the development of cardiac resistance to insulin-like growth factor I in ventricular myocytes," <i>Diabetes Res. Clin. Pract.</i> 55(2):89-98, February 2002.
	ANN	Holzenberger et al., "IGF-1 receptor regulates lifespan and resistance to oxidative stress in mice," <i>Nature</i> 421(6919):182-7, January 9, 2003, <i>Epub.</i> December 4, 2002.

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Other Documents (include Author, Title, Date, and Place of Publication)		
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	AOO	Melov et al., "Extension of life-span with superoxide dismutase/catalase mimetics," Science 289:1567-69, September 1, 2000.
	APP	Miller et al., "Gene expression patterns in calorically restricted mice: partial overlap with long-lived mutant mice," Mol. Endocrinol. 16(11):2657-66, November 2002.
	AQQ	Morris et al., "A phosphatidylinositol-3-OH kinase family member regulating longevity and diapause in <i>Caenorhabditis elegans</i> ," Nature 382(6591):536-9, August 8, 1996.
	ARR	Nargund et al., "Peptidomimetic growth hormone secretagogues. Design considerations and therapeutic potential," J. Med. Chem. 41(17):3103-27, August 13, 1998.
	ASS	Orrego et al., "Semiquantification of hypothalamic GH-releasing hormone output in women: evidence for sexual dimorphism in the mechanism of the somatopause," J. Clin. Endocrinol. Metab. 86(11):5485-90, November 2001.
	ATT	Pasternak et al. "Potent, orally bioavailable somatostatin agonists: good absorption achieved by urea backbone cyclization," Bioorg. Med. Chem. Lett. 9(3):491-6, February 8, 1999.
	AUU	Patchett et al. "Design and biological activities of L-163,191 (MK-0677): a potent, orally active growth hormone secretagogue," Proc. Natl. Acad. Sci. U S A. 92(15):7001-5, July 18, 1995.
	AVV	Root and Root "Clinical pharmacology of human growth hormone and its secretagogues," Curr. Drug Targets Immune Endocr. Metabol. Disord. 2(1):27-52, April 2002.
	AWW	Saeki et al., "Insulin-like growth factor-1 protects peroxynitrite-induced cell death by preventing cytochrome c-induced caspase-3 activation," J. Cell Biochem. 84(4):708-16, 2002.
	AXX	Sato et al. "Interference with PDK1-Akt survival signaling pathway by UCN-01 (7-hydroxystaurosporine)," Oncogene 21(11):1727-38, March 7, 2002.
	AYY	Schally et al., "Antagonistic Analogs of Growth Hormone-releasing Hormone: New Potential Antitumor Agents," Trends Endocrinol. Metab. 10(10):383-391, December 1999.
	AZZ	Shimokawa et al., "Life span extension by reduction in Growth Hormone-Insulin-Like Growth Factor-1 axis in a transgenic rat model," Am. J. Pathol. 160(6):2259-65, June 2002.
	AAAA	Swanson et al., "The growth hormone-deficient Spontaneous Dwarf rat is resistant to chemically induced mammary carcinogenesis," Carcinogenesis 23(6):977-82, June 2002.
	ABBB	Swerdlow et al., "Risk of cancer in patients treated with human pituitary growth hormone in the UK, 1959-85: a cohort study," Lancet 360:273-77, July 27, 2002.
	ACCC	Wen et al. "Typhostin AG 1024 modulates radiosensitivity in human breast cancer cells," Br. J. Cancer 85(12):2017-21, December 14, 2001.
	ADDD	Yang et al. "Synthesis and biological activities of potent peptidomimetics selective for somatostatin receptor subtype 2," Proc. Natl. Acad. Sci. U S A 95(18):10836-41, September 1, 1998.
	AEEE	Zarandi et al., "Synthesis and biological activities of highly potent antagonists of growth hormone-releasing hormone," Proc. Natl. Acad. Sci. U S A 91(25):12298-302, December 6, 1994.

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